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No. 05-656

IN THE

Supreme Court of the United States

MEDIMMUNE, INC.,

Petitioner,

v.

CENTOCOR, INC., *et al.*,

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF IN OPPOSITION

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QUESTION PRESENTED

Whether the Federal Circuit correctly decided that there is no case or controversy over a patent declaratory judgment action by a plaintiff-licensee in good standing who seeks to challenge a licensed patent where (a) the plaintiff's continued royalty payments ensure that it is maintaining all of the benefits of its license and has no reasonable apprehension of an infringement suit, and the plaintiff is seeking to challenge the licensed patent on the very same grounds that it raised during the license negotiations to obtain more favorable terms, and (b) allowing the action to proceed would subvert the purpose of the license by providing the licensee a safe platform from which to force the licensor to litigate in contravention of its own promise not to sue and with no ability to recover its full measure of damages.

CORPORATE DISCLOSURE STATEMENT PURSUANT TO SUPREME COURT RULE 29.6

Respondent Centocor, Inc. ("Centocor") has one parent corporation, Johnson & Johnson, which is the only publicly-traded corporation that owns 10% or more of Centocor's stock. The other two respondents, The Trustees of Columbia University in the City of New York and The Board of Trustees of the Leland Stanford Junior University ("the Universities"), are private academic institutions. No parent or publicly-held entity has any ownership interest in the Universities.

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BRIEF IN OPPOSITION

Respondents respectfully request that this Court deny the petition for writ of certiorari seeking review of the Federal Circuit's decision in this case.

STATUTORY PROVISIONS INVOLVED

28 U.S.C. § 1331 (federal question jurisdiction), 28 U.S.C. § 1338(a) (federal jurisdiction over, among other things, patents), and 28 U.S.C. § 2201(a) (Declaratory Judgment Act) are reproduced at Petitioner's Appendix ("Pet. App.") 41a. Petitioner also alleged that the district court had jurisdiction under 28 U.S.C. §§ 2202 and 1332.

STATEMENT OF THE CASE

A. Background Leading To The Litigation

This case involves U.S. Patent No. 5,807,715 ("the '715 patent"). The '715 patent issued on September 15, 1998 and is entitled *Methods and Transformed Mammalian Lymphocytic Cells for Producing Functional Antigen-Binding Protein Including Chimeric Immunoglobulin and Fragments.* The patent reflects the work of prominent research scientists in the field of monoclonal antibody technology. The Trustees of Columbia University in the City of New York ("Columbia University") and The Board of Trustees of the Leland Stanford Junior University are the assignees of the patent, and Centocor is the exclusive licensee.

Petitioner, MedImmune, Inc. ("MedImmune"), learned of the '715 patent shortly after it issued and called Columbia University to inquire about a license. CAA. 1200-01, 1212.[1] A representative of Columbia University informed MedImmune that Centocor was the exclusive licensee. CAA. 1212. Around that same time, MedImmune asked its regular outside patent counsel to evaluate the '715 patent, including whether it was valid and infringed by MedImmune's product Synagis®. CAA. 1200-01.

Centocor, as part of its sublicensing obligations to the Universities, wrote MedImmune on May 19, 1999, to offer it a sublicense to the '715 patent. CAA. 1223. The letter did not mention or threaten litigation. *Id.* In response to Centocor's offer to discuss a license, MedImmune advised Centocor that "MedImmune and its outside patent counsel have reviewed [the '715] patent . . . and have concluded that we do not infringe any valid patent claim." CAA. 573. MedImmune continued to consult with outside counsel and

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[1] Citations to "CAA." are to the joint appendix filed in the Court of Appeals.

hired another law firm for a second opinion on the issues of infringement and invalidity. CAA. 1247, 1418.

In May 2000, following talks between business and legal representatives of both companies, representatives of MedImmune and Centocor met to discuss the terms of a possible sublicense. CAA. 1511-12. During the May 2000 meeting, MedImmune again asserted that the '715 patent was not infringed or valid, and also claimed that MedImmune could design around the patent. CAA. 1421-28. Notwithstanding these arguments, the parties began extensive negotiations over the terms of the sublicense, including the royalty rate. CAA. 1223. Over the next several months, Centocor twice lowered its proposed royalty rate and agreed to forego past royalties for a two-year period in an effort to reach a compromise and after MedImmune voiced concerns about its other royalty obligations on Synagis®. CAA. 1424-25.

MedImmune executed the Sublicense Agreement on December 29, 2000, and began paying royalties on Synagis®. Each MedImmune officer involved in the negotiations testified that MedImmune entered into the Sublicense Agreement and began to pay royalties to eliminate any risk of litigation and an injunction against Synagis® and to cap its damages. CAA. 1220-21, 1229-32, 1386-87, 1500. Synagis® is the only product for which MedImmune has ever paid royalties under the Sublicense Agreement. CAA. 1220.[2]

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[2] As required by Supreme Court Rule 15(2), Respondents point out perceived misstatements in the Petition. The Petition states that Centocor threatened litigation and forced MedImmune to enter into the Sublicense Agreement and pay royalties. *See* Pet. at 3, 21. While these statements have no bearing on whether a case or controversy exists over the present action, because the parties' Sublicense Agreement resolved any disputes the parties may have had concerning the '715 patent and both sides are performing under the Agreement, Respondents nevertheless point out that the statements are inaccurate. MedImmune relied below solely upon an email and conversations between principals of the parties in support of its

Centocor, the Universities, and the inventors ordered their affairs around those royalty payments, and had no reason to suspect that MedImmune wanted to undermine the agreement. Meanwhile, mere days after MedImmune executed the Sublicense Agreement, MedImmune faxed a copy of the agreement to its current litigation counsel. CAA. 1413-14. For at least a year after the Sublicense Agreement was executed, MedImmune assessed its litigation options with respect to the '715 patent. MedImmune's Board of Directors authorized the filing of the lawsuit after being briefed repeatedly on the matter between February 15, 2001 (less than two months after the Sublicense Agreement was signed) through at least February 21, 2002. CAA. 1266, 1272, 1274, 1284, 1291. The minutes from MedImmune's February 21, 2002 Board of Directors' meeting reveal that the decision to file suit was based upon purely financial considerations. CAA. 1291.

On April 5, 2002, MedImmune filed a declaratory judgment action against Centocor in the United States District Court for the District of Maryland. CAA. 42. The complaint sought a declaration of MedImmune's rights and obligations under the Sublicense Agreement, and alleged that Synagis® did not infringe any of the claims of the '715 patent and that the patent was invalid and unenforceable. CAA. 42-59. MedImmune did not stop paying royalties to Centocor before filing its complaint. It has continued to make royalty payments throughout this litigation, and has stated that it does not intend to terminate the Sublicense Agreement. CAA. 515.

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allegations of threats and pressure. These communications, however, were congenial and reflected nothing more than a desire on Centocor's part to finalize the agreement. CAA. 1576, 1568, 2695-97, 1565-67, 131, 2697. Moreover, MedImmune's principal failed to substantiate MedImmune's allegation of threats at his deposition. CAA. 2525-27. Finally, MedImmune has waived any claim of duress in this case. *See* CAA. 515.

Because MedImmune's original April 2002 complaint was filed against Centocor alone and did not name the Universities (the owners of the '715 patent), the Universities and Centocor filed on July 9, 2002, a mirror-image declaratory judgment action against MedImmune in the United States District Court for the Northern District of California (the "California Action"). CAA. 135-43. The California Action was filed in order to add the Universities to the case in a forum in which they were subject to personal jurisdiction (*see* CAA. 138), and because California was a more convenient forum for key inventorship- and patent prosecution-related fact witnesses. CAA. 89.

MedImmune moved to dismiss the California Action for failure to state a claim upon which relief can be granted under the first-filed doctrine and/or under the Court's discretion to decline to exercise jurisdiction under the Declaratory Judgment Act. On October 21, 2002, the California district court granted MedImmune's motion to dismiss. CAA. 1405-11. The case was dismissed for two reasons: (1) because there was "no indication that MedImmune would discontinue performance of its obligations under the sublicense and thus infringe the patent," and thus "there is no actual controversy to satisfy the Declaratory Judgment Act"; and (2) in deference to the previously-filed Maryland action. CAA. 1409-11.

B. The Proceedings Before The District Court

The Universities initially filed a motion to dismiss for lack of a case or controversy in the present action on June 30, 2003. The District Court denied that motion. On March 5, 2004, the Federal Circuit issued its decision in *Gen-Probe, Inc. v. Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir. 2004). In the *Gen-Probe* decision, the Federal Circuit, applying its two-part case or controversy test, held that a district court does not have subject matter jurisdiction over a licensee's declaratory judgment suit when the licensee is in good standing and

continues to pay royalties under the license agreement. *Id.* at 1380-82. The Federal Circuit explained that the license, "unless materially breached, obliterated any reasonable apprehension of a lawsuit," and that once the licensor and licensee "formed the license, an enforceable covenant not to sue, the events that led to the formation [of the license] became irrelevant." *Id.* at 1381.

In light of the *Gen-Probe* decision, Respondents again filed before the District Court a motion to dismiss for lack of jurisdiction. In dismissing the action below, the District Court found that MedImmune, like the licensee in *Gen-Probe*, had not established an actual controversy. Pet. App. 37a. The District Court further stated that it found the conclusions of the Federal Circuit "compelling" and "controlling." Pet. App. 38a.

C. The Federal Circuit's Affirmance

The Federal Circuit affirmed the District Court's dismissal. The court reviewed the nature of the Declaratory Judgment Act and Article III and explained that "[t]o keep watch over the subtle line between an 'abstract question' and 'a controversy contemplated by the Declaratory Judgment Act,' . . . an inquiry has been formulated that focuses on the conduct of both the patentee and the accused infringer." Pet. App. 4a-5a. The court further explained that "[w]hen a potential infringer seeks declaratory relief in the absence of a lawsuit by the patentee, there must be both (1) a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit; and (2) present activity by the declaratory judgment plaintiff which could constitute infringement, or concrete steps taken with the intent to conduct such activity." Pet. App. 5a.

The Federal Circuit reviewed its *Gen-Probe* decision and agreed with the district court that *Gen-Probe* was determinative. The court then held that the Sublicense

Agreement eliminated any pre-license controversy alleged by MedImmune:

> Any controversy that may have existed between MedImmune and Centocor prior to and during their various negotiations vanished when MedImmune executed the license agreement, which is a covenant by Centocor not to sue. Quite simply, once the license agreement was in place and MedImmune was in compliance with the terms of the agreement, MedImmune could not be under a reasonable apprehension that it would face an infringement suit by Centocor.

Pet. App. 5a-6a.

The Federal Circuit rejected MedImmune's arguments that the *Gen-Probe* decision was inconsistent with precedent of this Court, specifically *Cardinal Chemical Co. v. Morton Int'l*, 508 U.S. 83 (1993) and *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969), explaining that neither case concerned the issue of patent declaratory judgment jurisdiction. Pet. App. 6a-8a. The Federal Circuit similarly disagreed with MedImmune's argument that the *Gen-Probe* decision was inconsistent with the Federal Circuit's own precedent.[3] Pet. App. 8a-9a. The court also rejected MedImmune's argument that Respondents' suit against MedImmune *after* the filing of MedImmune's declaratory judgment suit altered the analysis, stating "[t]he presence or absence of a case or controversy is based on facts at the time the complaint was filed." Pet. App. 9a (citing *GAF Bldg Materials Corp. v. Elk Corp. of Dallas*, 90 F.3d 479, 483 (Fed. Cir. 1996)).

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[3] The Federal Circuit further rejected MedImmune's assertion that the Sublicense Agreement permitted this suit because it did not contain an agreement not to litigate. The court stated that "[t]his assertion overlooks the fact that a license is, by its nature, an agreement not to litigate." Pet. App. 6a n.1.

Petitioner filed a petition for rehearing and rehearing *en banc*, which the Federal Circuit unanimously denied. Pet. App. 40a.

REASONS FOR DENYING THE PETITION

Petitioner MedImmune seeks review by this Court in order to change the "actual controversy" standard for patent cases brought under the Declaratory Judgment Act. MedImmune's Petition presents the specific question of whether a licensee (in this case a sublicensee) may challenge a licensed patent while the licensee continues to make royalty payments to ensure that it retains all of the benefits of its license. The Federal Circuit correctly decided that there is no case or controversy over such a suit. Far from being a change in the law, that decision, and the Federal Circuit's earlier decision in *Gen-Probe*, are consistent with long-standing Federal Circuit law, firmly grounded in this Court's precedent, and compatible with case law from the other circuit courts.

The decisions below and in *Gen-Probe* were correct. MedImmune's petition ignores the simple fact that the Sublicense Agreement resolved any disputes that the parties may have had regarding the '715 Patent. The parties to the Sublicense Agreement are performing, and no disputes have arisen other than MedImmune's unilateral decision to challenge the licensed patent on the same grounds it raised when it sought to drive down the royalty rate during the license negotiations. There is thus no immediate controversy at this time as MedImmune faces no possible threat of infringement litigation and merely seeks to subvert the purpose of the Sublicense Agreement into which it voluntarily entered.

MedImmune incorrectly asserts that "the *Gen-Probe* doctrine" effectively eliminated declaratory judgment suits by patent licensees against their licensors in contravention of *Lear v. Adkins*, 395 U.S. 653 (1969). *See* Pet. at 8. In *Lear*, the license agreement was breached and there was no reason

for this Court to consider the question of whether a patent licensee may file suit *while maintaining the benefits of its license*. Here, Respondents gave up their right to sue MedImmune and obtain the full range of remedies provided under the patent laws by entering into the Sublicense Agreement and agreeing to a negotiated royalty rate. Correspondingly, MedImmune obtained protection from any suit in exchange for the payment of agreed upon royalties. Yet, MedImmune would force Respondents to defend themselves in this litigation in contravention of their own contractual covenants and with Respondents having no ability to recover their full measure of damages. Prohibiting Respondents from exercising these rights while simultaneously permitting MedImmune to litigate would create an inequitable imbalance in the licensing system that was never contemplated by *Lear*. Thus, and as explained more fully below, Respondents respectfully request that the writ be denied.

I. THE FEDERAL CIRCUIT'S *GEN-PROBE* DECISION IS NOT A CHANGE IN THE LAW

MedImmune contends that the Federal Circuit's *Gen-Probe* decision, upon which dismissal below was based, sets a "new" and "arbitrary" standard for determining declaratory judgment jurisdiction. *See* Pet. at 12. To the contrary, the *Gen-Probe* court merely applied the two-part test that the Federal Circuit has used for more than twenty years in determining whether a case or controversy exists in patent actions. *See Teva Pharms. USA, Inc. v. Pfizer Inc.*, 395 F.3d 1324, 1331 (Fed. Cir. 2005); *EMC Corp. v. Norand Corp.*, 89 F.3d 807, 810 (Fed. Cir. 1996); *Spectronics Corp. H.B. Fuller Co.*, 940 F.2d 631, 634 (Fed. Cir. 1991); *Cordis Corp. v. Medtronic, Inc.*, 835 F.2d 859, 862 (Fed. Cir. 1987); *Jervis B. Webb Co. v. S. Sys., Inc.*, 742 F.2d 1388, 1398 (Fed. Cir. 1984).

The two-part test is firmly rooted in this Court's precedent. Indeed, the Federal Circuit has repeatedly relied upon this Court's statements in *Maryland Cas. Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941) that the presence of an "actual controversy" within the meaning of the Declaratory Judgment Act depends on "whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient *immediacy* and reality to warrant the issuance of a declaratory judgment." *See, e.g., Teva*, 395 F.3d at 1331; *Gen-Probe*, 359 F.3d at 1379-80. In the patent context, the Federal Circuit looks to the conduct of both parties (thus the two-part test) to determine whether there is an immediate patent infringement controversy. *Teva*, 395 F.3d at 1332; *Gen-Probe*, 359 F.3d at 1380.[4]

MedImmune has objected to the application of the two-part test to a declaratory judgment plaintiff who is a licensee in good standing. However, it was neither new nor arbitrary for the Federal Circuit to apply its declaratory judgment standard to a patent licensee. In *C.R. Bard, Inc. v. Schwartz*, 716 F.2d 874 (Fed. Cir. 1983), the Federal Circuit applied a "reasonable apprehension of an infringement suit" test to a licensee-plaintiff to determine whether a case or controversy existed over its declaratory judgment action for invalidity of the licensed patent while the patent license was in effect. *Id.* at 879-81. Because the licensee-plaintiff in *Bard* (unlike MedImmune here) had stopped paying royalties, the Federal Circuit determined that the plaintiff faced a real risk of suit, which satisfied the requirements for a declaratory judgment action. In another Federal Circuit decision, the court stated:

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[4] The two-part test is: (1) a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit; and (2) present activity by the declaratory judgment plaintiff which could constitute infringement, or concrete steps taken with the intent to conduct such activity. *See, e.g., Teva*, 395 F.3d at 1331.

"a licensee . . . cannot invoke the protection of the Lear doctrine until it (i) actually ceases payment of royalties, and (ii) provides notice to the licensor that the reason for ceasing payment of royalties is because it has deemed the relevant claims to be invalid." *Studiengesellschaft Kohle, m.b.H. v. Shell Oil Co.*, 112 F.3d 1561, 1568 (Fed. Cir. 1997).

II. THE FEDERAL CIRCUIT'S DECISION BELOW AND IN *GEN-PROBE* WERE CORRECT

The decisions below, and the earlier *Gen-Probe* decision, were correct. In *Gen-Probe,* the Federal Circuit carefully considered the competing interests of licensors and licensees to confirm that the two-part test applies in the patent license context. 359 F.3d at 1382. As the court explained, licensors would unjustly bear all of the risks of a licensee's challenge if the licensee were permitted to bring a suit challenging a licensed patent without giving up the protection of its license. *Id.*

The Federal Circuit's rationale is compelling. There is a contractual parity that provides an incentive for parties to enter into license agreements and share technology. By granting the license, the licensor, at a minimum, gives up the ability to enforce the patent at a time and in an appropriate forum of its choosing, and to recover damages in excess of the compromised royalty rate, potentially enhanced damages for willful infringement, and an injunction. The licensee is immune from these risks by virtue of being licensed and in exchange for the payment of royalties.

Before *Lear*, licensee estoppel disrupted this parity and provided licensors with considerable power over their licensees where, after entering into a license agreement, the licensee concluded that a licensed patent was invalid or unenforceable. Pre-*Lear,* the licensee faced a no-win situation: if it stopped making royalty payments, it would not be allowed to defend itself in a subsequent breach of contract

action by asserting that such patent was invalid or unenforceable. *Lear* abolished the doctrine of licensee estoppel in such circumstances to eliminate this inequity.

MedImmune seeks to swing the pendulum too far in the opposite direction, placing too much power into the hands of a licensee who wants to challenge a licensed patent at the expense of the licensor. Indeed, the licensor would stand to lose its right to continue receiving royalty payments, have to pay for the very litigation it contracted to avoid, and have no chance of any recovery other than that to which it was already contractually entitled. The licensee, on the other hand, would risk nothing by a challenge to the licensed patent other than its litigation fees. Even if the challenge failed, the licensee would continue to enjoy the same immunities and benefits under the license agreement at the same royalty rate.

If MedImmune's position were accepted, a licensee would be permitted to challenge a licensed patent essentially *whenever* it wanted without giving up any benefits under the license. This result would be at odds with the "immediacy" requirement for a constitutional case or controversy, as jurisdiction could be established at any time. *See Maryland Cas.*, 312 U.S. at 273. In addition to greatly enlarged patent jurisdiction, licensors would also be forced to live in continued fear of suit from their licensees, a result contrary to the very purpose of the Declaratory Judgment Act. *See Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 734-735 (Fed. Cir. 1988). Licensees, on the other hand, would be encouraged to enter into agreements to insulate their risk and gain the benefit of licensed technology and then evade the equities of those agreements by forcing licensors to defend against patent challenges without a full range of remedies.[5]

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[5] Such a result would discourage licensing, which fosters competition by making technology and intellectual property more widely available.

The decisions in *Gen-Probe* and this case thus strike the appropriate balance of power between the licensor and licensee. A party may challenge a patent that it has licensed as in *Lear*, but it cannot do so while maintaining and enjoying its rights under the license. Indeed, as the Federal Circuit below explained, every potential infringer "must decide to settle or fight." Pet. App. 10a. MedImmune's attempt to afford itself the ability to do both is fundamentally unfair to licensors.

III. THIS CASE INVOLVES PATENT AND NOT CONTRACT JURISDICTION

MedImmune argues that *Gen-Probe* conflicts with contract declaratory judgment case law and policy, particularly *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240-41 (1937). In citing contract case law, MedImmune neglects the fact that, to the extent that there is a controversy here, it is grounded in patent rather than general commercial law. Indeed, the issues MedImmune sought to litigate are purely patent in nature: invalidity, noninfringement and unenforceability.[6] These are the very same issues that MedImmune raised and could have sought to litigate *instead of* signing the Sublicense Agreement.

Alternatively, the only way prospective licensors could ensure themselves of the benefit of their bargain would be by filing suit first and then entering into a license agreement as part of a consent decree or settlement agreement. The licensor would thereby obtain *res judicata* of the licensees' patent claims. *See Foster v. Hallco Mfg. Co.*, 947 F.2d 469 (Fed. Cir. 1991). Encouraging licensors to file suit when they are considering granting a license would have the undesired effect of overburdening the federal court system and slowing down the licensing cycle, thereby creating unnecessary delays in taking products to market.

[6] MedImmune's "Question Presented" confirms that the underlying action is patent in nature. Moreover, in order to avoid arbitration, MedImmune argued successfully before the District Court that this action was a patent dispute, not a contract dispute. CAA. 513, 536.

By contrast, a true contract dispute is one that has *arisen from* the contract itself and would not exist independently. These cases generally involve the application of the parties' agreement to circumstances arising *after* execution of the contract. *See e.g., Aetna*, 300 U.S. at 237-38; *Keener Oil & Gas Co. v. Consol. Gas Utilities Corp.*, 190 F.2d 985, 989 (10th Cir. 1951); *Am. Machine Metals Inc. v. De Bothezat Impeller Co.*, 166 F.2d 535, 536 (2d Cir. 1948). Unlike those cases, MedImmune is not seeking to interpret a contractual provision or to resolve a good faith dispute that has arisen from the contract. Instead, the only dispute here is the one that MedImmune unilaterally created by raising the same challenges to the '715 patent that it asserted *before* signing the Sublicense Agreement.

Moreover, there is a fundamental difference between patent litigation involving parties to a license agreement and general contract declaratory judgment actions. As explained above, a patent license by its very nature is a covenant not to sue based on the licensed patent in exchange for a compromised royalty rate. *See* Pet. App. 6a n.1. Thus, through the present type of action, a patent licensee would not only undermine its license agreement, it would do so in a manner that strikes at the very heart of the consideration for the agreement. Such a challenge would place the licensor in a uniquely unfair position—the licensor loses its contractual benefits of foregoing litigation and stands to lose the negotiated royalties but has no ability to seek the full measure of damages to which it would have been entitled had it not entered into the license agreement. There is no analogous issue in the contract cases relied upon by MedImmune as general contracts typically do not include a covenant not to sue as part of the bargained-for consideration.

As this Court has explained, Congress created the Court of Appeals for the Federal Circuit to increase uniformity in patent-related decisions. *See Markman v. Westview Instr. Inc.*, 517 U.S. 370, 390 (1996). The Federal Circuit has been

consistent in its application of an "actual controversy" standard in patent cases. *See supra* Section I. MedImmune has not presented any compelling reason to upset the settled expectations of litigants and deviate from long-standing Federal Circuit law in favor of some other standard derived from contract declaratory judgment case rulings that have no sensible application to this case.

IV. THE FEDERAL CIRCUIT'S DECISION DOES NOT CONFLICT WITH THE DECISIONS OF THIS COURT OR OTHER COURTS OF APPEAL

A. Precedent Of This Court

The case law relied upon by MedImmune does not establish a conflict in the law. MedImmune argues that *Gen-Probe* is "irreconcilable" with this Court's decision in *Lear*, 395 U.S. 653 (1969). Specifically, MedImmune suggests that *Lear* permits its present action, but that the Federal Circuit has eroded *Lear* over time, effectively eliminating it with the *Gen-Probe* holding. *See* Pet. at 18-19. The *Gen-Probe* and *Lear* decisions, however, present no conflict. *Lear* originated as a state court breach of contract action filed by the licensor after the licensee had stopped paying royalties under a license agreement. 395 U.S. at 659-60. The Court held that, as a matter of public policy, the licensee was not estopped from asserting patent invalidity as a defense in the breach of contract action. *Id.* at 673-74. *Lear* never addressed the question presented in *Gen-Probe* of whether there is a case or controversy over a licensee's challenge to a licensed patent while the licensee is maintaining the protection of its license.[7]

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[7] MedImmune cites *Diamond Scientific Co. v. Ambico, Inc.*, 848 F.2d 1224 (Fed. Cir.), *pet'n for cert. dismissed*, 487 U.S. 1265 (1988) and *Kohle*, 112 F.3d at 1561, to support its contention that "*Lear* has been under attack for years" in the Federal Circuit. *See* Pet. at 19. While both of those cases involved facts different from those in *Lear*, the Federal Circuit nevertheless carefully considered the principles of *Lear* and

Like the licensee in *Lear*, MedImmune is free to challenge the licensed patent and nothing in *Gen-Probe* prevents it from making the choice to stop making royalty payments and assert such a challenge.

MedImmune also relies on *Altvater v. Freeman*, 319 U.S. 359 (1943) in attempting to establish that *Gen-Probe* conflicts with decisions of this Court. In *Altvater*, this Court expressly stated that it was *not* considering the question of whether a licensee—*i.e.*, a party who *voluntarily* pays for the use of a licensed patent—can challenge the validity of the patent. *See id.* at 364. Indeed, the Court stated, "[w]e can put to one side . . . [whether] a *licensee* is estopped to challenge the validity of a patent . . . " *Id.* Of significance to the *Altvater* Court's opinion was the fact that the lower courts had determined that the license agreement had been terminated and that plaintiff was involuntarily paying royalties "under the compulsion of an injunction decree" from an earlier litigation involving a patent that had been surrendered to the Patent Office in a reissue proceeding. *Id.* at 365. Thus, *Alvater* is readily distinguishable on its facts.

MedImmune further argues that *Gen-Probe* conflicts with *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240-41 (1937). As explained above, *Aetna* does not address declaratory

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followed *Lear*'s approach of weighing the equities to determine whether federal patent policies would be "significantly frustrated" by enforcing contractual covenants. *See Diamond*, 848 F.2d at 1224 (holding that the assignor-inventor was estopped from defending against an infringement action by challenging the validity of the patents it assigned because "[t]o allow the assignor to make that representation [of the worth of the patent] at the time of the assignment (to his advantage) and later to repudiate it (again to his advantage) could work an injustice against the assignee . . ."); *Kohle*, 112 F.3d at 1568 (holding that the lower court could enforce a license for the period of time before the licensee's challenge to the validity of the licensed patent because of the licensee's delay in timely challenging the patent to the detriment of the public). Thus, the Federal Circuit has not undermined this Court's decision in *Lear*.

judgment jurisdiction over a patent action. Other facts in *Aetna* also clearly distinguish it from *Gen-Probe* and the present case. In *Aetna*, the insured had stopped making premium payments on the grounds that his disability relieved him of such obligation. 300 U.S. at 239, 242. The insurance company disagreed that the insured was disabled and sought declaratory judgment that four policies had lapsed due to non-payment and that the company had no obligation to provide certain benefits. *Id.* The Court indicated that the insured could have brought suit at any point demanding benefits. *Id.* at 243. This case does not present a comparable fact pattern: at no point after the Sublicense Agreement was signed could respondents have sued MedImmune. The *Aetna* case is not "even remotely similar or analogous" to the circumstances present in *Gen-Probe* or this case. 359 F.3d at 1382.

B. Decisions From Other Circuit Courts

MedImmune attempts to establish a conflict among the circuit courts, arguing that the *Gen-Probe* decision is "not logically limited to patent licenses" and "affects basic federal law through the country." *See* Pet. at 10. This argument ignores the fundamental point that *Gen-Probe* considered whether a case or controversy existed in a *patent* dispute. As explained above, there is a significant difference between a *patent* declaratory judgment action between parties to a license agreement and a non–patent *contract* declaratory judgment action. Regardless, a review of the case law cited by MedImmune demonstrates that there is no conflict between the Federal Circuit's application of the two-part declaratory judgment standard and decisions of other circuit courts.

MedImmune quotes *Sallen v. Corinthians Liceniamentos LTDA*, 273 F.3d 14 (1st Cir. 2001), to support its contention that other circuits have recognized that an Article III case or controversy may be established in the absence of "apprehension of a lawsuit." In *Sallen*, however, the court merely determined that application of the "reasonable apprehension

of suit" test was not necessary because the domain name dispute "had already *progressed far beyond* . . . cases in which a declaratory defendant only questionably threatened suit." *Id.* at 26 (emphasis added). Indeed, the plaintiff had already been brought before a World Intellectual Property Organization ("WIPO") panel, lost the use of its domain name through WIPO dispute resolution proceedings, and was seeking through its declaratory action to overturn the decision of the WIPO proceeding. *Id.* The court specifically contrasted these facts with cases where the controversy surrounds a potential, future lawsuit, for which the court indicated the "reasonable apprehension of suit" test would govern. *Id.* at 25. Thus, far from establishing a split among circuit courts, this case is consistent with Federal Circuit law.

MedImmune also argues that the *Gen-Probe* line of cases "cannot be reconciled with the law applied to licenses of intellectual property in other circuits." Pet. at 17 (citing *Hal Roach Studios, Inc. v. Richard Feiner & Co.*, 896 F.2d 1542, 1556 n. 23 (9th Cir. 1990); *Société de Conditionnement v. Hunter Engineering Co.*, 655 F.2d 938, 943-44 (9th Cir. 1981)). Neither case involved the issue presented in *Gen-Probe*. *Hal Roach* involved a suit by a copyright owner/licensor—and not a licensee—seeking a declaration that the license agreement would expire on a certain date and that the licensor had valid copyrights. 896 F.2d at 1544-45. The licensee, among other things, raised copyright invalidity as an affirmative defense. *Id.* at 1553. Thus, the facts are very different from the present case.

MedImmune's reliance on *Société* is also misplaced. Contrary to MedImmune's argument, *Société* did not concern a declaratory judgment action between parties to a patent license or any other type of contract. *See* Pet. at 17. Instead, the plaintiff filed suit against a competitor after the competitor's technical director threatened a mutual customer with patent litigation to deter the customer from purchasing

additional products from the plaintiff, and the customer requested an indemnity. 655 F.2d at 940-41. Although *Société* was decided before the creation of the Federal Circuit, the case or controversy standard that the court applied (whether "the plaintiff has a real and reasonable apprehension that it will be subject to liability if he continues to manufacture his product") is not significantly different from the Federal Circuit's two-part test. *See id.* at 944. Thus, this case also presents no conflict with Federal Circuit law.

MedImmune argues that *Gen-Probe* is incompatible "with federal law on declaratory actions involving licenses and other contracts generally." Pet. at 17-18 (citing *Keener Oil & Gas Co. v. Consol. Gas Utilities Corp.*, 190 F.2d 985, 989 (10th Cir. 1951); *Am. Machine Metals Inc. v. De Bothezat Impeller Co.*, 166 F.2d 535, 536 (2d Cir. 1948)). As explained in section III above, those cases are inapplicable because they involve contractual disputes arising from the agreements at issue.[8]

V. THE DECISION BELOW RESTS ON SOUND PUBLIC POLICY

MedImmune's final argument focuses on risk, and asserts, incorrectly, that the Federal Circuit decision in this case and other cases following *Gen-Probe* somehow put licensees at a disadvantage in challenging patents they believe to be invalid or unenforceable.

License agreements, by their nature, are risk management tools. In order to avoid the risks inherent in litigation over a patent and a potentially infringing product, the parties agree on a licensing arrangement and negotiate a royalty rate commensurate with their respective risk assessments. That is

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[8] MedImmune further cites to decisions pre-dating the creation of the Federal Circuit. The Federal Circuit has resolved any conflict presented in those decisions.

how the licensing system works in the United States and neither *Gen-Probe* nor the decision below will change that. Rather, these cases promote licensing, by encouraging established companies to grant licenses to newer, younger businesses, knowing that they can rest assured that the license agreement will provide a safe haven for them to share technology in an agreed-upon, negotiated setting.

MedImmune wants to change this negotiated equipoise so that all of the risk is borne by the licensor, leaving the licensee free to challenge the patent at a moment's notice, without losing the safety net of the license agreement. MedImmune describes its position as a way of "restor[ing] the balance enacted by Congress in the patent laws." *See* Pet. at 22. In fact, MedImmune seeks to skew the balance entirely in favor of licensees, thereby throwing into disarray the settled expectations of parties who participate in the license system, and in all likelihood, discouraging patent holders from entering into license agreements with start-up companies with unproven track records in terms of their willingness to honor and abide by a negotiated license and not file suit.

MedImmune also argues that the holding of *Gen-Probe* is particularly unjust to smaller/startup companies, characterizing itself as such a company that was threatened and forced by a big company to pay royalties or else risk losing its business. This characterization is unfounded as explained above. *See supra* n.2. MedImmune is a sophisticated company that exercised its business judgment to enter the Sublicense Agreement only after a lengthy period of negotiation, during which MedImmune received advice and opinions from at least two law firms and asserted a number of invalidity and non-infringement arguments to negotiate down the proposed royalty rate. MedImmune does not need or warrant special protection from the Court, especially protection that runs contrary to the legal and public policy reasons discussed above.

CONCLUSION

For all of the foregoing reasons, the Court should deny MedImmune's petition for writ of certiorari.

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